



National Pork Producers Council

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8368 '99 SEP 30 P1:27

September 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99N-1591

Dear Sir or Madam:

Pork producers have a vital interest in the timely, economical availability of effective products to address the health concerns of our animals. We worked diligently for the passage of the Animal Drug Availability Act of 1996 (ADAA) and would like to comment on the proposed regulations relating to the distribution and use of Veterinary Feed Directive (VFD) drugs and animal feeds containing VFD drugs, Docket No. 99N-1591.

The following comments are submitted on behalf of the National Pork Producers Council (NPPC), which represents the nation's pork producers through 44 affiliated state associations. Our members account for the overwhelming majority of this nation's commercial pork production. The pork industry is one of the largest agricultural sectors in this country, generating approximately \$11.0 billion in annual farm sales (although farm gate sales were reduced to approximately \$9.0 billion in 1998 as a result of the lowest prices in history in deflated dollars). In addition, the pork industry creates an estimated \$64.0 billion in economic activity and supports an estimated 600,000 jobs.

It is important that producers and their veterinarians have available treatment options that can effectively, quickly, and economically deal with diseases that affect swine herds. This is because the health of the nation's swine herd, their welfare, and their safety as a food protein source for the nation's consumers are dependent on the ability of the producers and their veterinarians to prevent or treat disease when antimicrobials are indicated.

99N-1591

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The Other
White Meat

The FDA has asked for comments on the proposed approach to regulating VFD use through expiration dates and reorder restrictions. During modern pork production, groups of pigs are scheduled to move through the production system at regular, timed intervals. This necessitates, for example, that groups of females are bred and farrowed together, their pigs are weaned together, and they go to market together. It is not unusual for weaning to take place on a regular basis, such as at weekly intervals. Should a disease strike at weaning into a nursery, each group of pigs entering the nursery will be at risk until the disease is brought under control. It is important that the producer and the veterinarian have the flexibility to use the VFD to address disease prevention, control, and treatment fitting with these production practices.

Because of this, it is important to producers, the welfare of their animals, and the safety of the nation's meat supply that VFD use in multiple, at-risk production groups, ordered by a veterinarian under a valid VCPR, be permitted and differentiated from continued use in a particular group of pigs. Producers realize that continued use of a VFD product in a specific group of pigs is unwise and would significantly add to the cost of production. Allowing a single VFD to apply to multiple production groups recognizes the realities of modern production and is differentiated from continued use. And, allowing an individual VFD to last for up to six months for a particular production facility and its multiple production groups of pigs, given proper identification and calculation of the expected amount of drug needed and the expected consumption of feed, reasonably permits use flexibility.

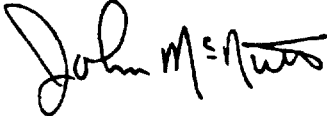
In addition, requiring a completely new VFD to be written for each group that is at particular risk to exposure of a disease would be disruptive to the producer and veterinarian. It would also significantly add to production costs if the veterinarian charges a fee for the individual VFDs that could be written as one.

The FDA also has asked for comments on how to ensure transmission of clear, complete, and secure VFD information. With the rapid development of new and increasingly secure methods of data transmission, NPPC urges the agency to not limit the transmission to only today's technology. Including the provision for suitably secure transmission that could be provided by controlled access to web sites, etc. would allow for a variety of communication methods that may not yet be available but could yet be secure even without redundant paperwork. The objective would be to offer multiple methods of transmission that will facilitate a quick response to a

disease threat. Today's uses of fax or e-mail are two contemporary examples.

Thank you for the opportunity to comment on the proposed regulations. Pork producers continue to appreciate the opportunity the ADAA has furnished regarding the availability of VFD products as they strive to provide the nation's consumers with the safest pork product in the world.

Sincerely,

A handwritten signature in black ink, appearing to read "John McNutt". The signature is fluid and cursive, with the first name "John" being more prominent than the last name "McNutt".

John McNutt
NPPC President



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